

Remarks

Claims 54, 58, 59, 61, 65 and 66 have been amended, claims 95-107 have been added, claims 76-94 are withdrawn, claims 55, 56 and 62 have been cancelled. Following this amendment claims 54, 57-61 and 63-107 will be pending with claims 76-94 being withdrawn. Support for the claims as amended may be found for instance, on page 2, lines 2-9, page 3, lines 26-30, page 4, lines 16-18, page 6, lines 1-16 the examples and throughout the application as originally filed. No new matter is added as a result of this amendment. Applicants believe the current amended claims and remarks below address the Examiner's remaining concerns.

Objections

The Examiner objected to claims 65 and 59 in view of minor typographical errors. Applicants appreciate the Examiner's suggestions and have amended the claims accordingly.

The objection is respectfully obviated.

Rejection Under 35 U.S.C. § 112 ¶2

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54-75 were rejected as being indefinite for lacking sufficient antecedent basis for the phrase "domains or pockets" as the previous line stated only a "domain or pocket". Applicants have amended the claim language to recite the phrase "domain or pocket". The specification as filed and the claim support the protection of the active agent through more than one domain, however, Applicants believe the claim language now more clearly recites that at least one active agent is protected in at least one domain or pocket.

The rejection is respectfully obviated.

35 U.S.C. §102(b)

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in a public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54-56, 59-60, 62, 66 and 71 were rejected under 35 U.S.C. §102(b) as anticipated by Peterson et al. (U.S. Patent 4,356,166). "Anticipation under 35 U.S.C. § 102 requires the

disclosure in a single piece of prior art of each and every limitation of a claimed invention.” (*Electro Med. Sys. S.A. v. Cooper Life Sciences*, 32 U.S.P.Q.2d 1017, 1019 (Fed. Cir. 1994)). The claim as amended is directed to a pharmaceutical composition comprising an active agent non-covalently protected in an internalized domain or pocket of an amino acid polymer wherein the amino acid polymer structure comprises at least one hydrophilic/polar component and at least one hydrophobic/non-polar component designed to promote the formation of the internalized domain or pocket; and the hydrophilic/polar component and hydrophobic/non-polar component are selected to manipulate the tertiary structure of the amino acid polymer to control degradation and release of the active agent and wherein the hydrophilic/polar component is lysine, arginine, asparagine, cysteine, glutamic acid or combinations thereof; and wherein the hydrophobic/non-polar component is valine, tyrosine, proline, leucine, tryptophan, methionine, phenylalanine, glycine, isoleucine, benzyl glutamic acid, or combinations thereof.

The Examiner states that Peterson et al. teach a pharmaceutical compositions comprising (i) an active agent and (ii) an amino acid polymer and various amino acids of varied length. Applicants have amended the claim to clarify that the active agent is not covalently attached to the amino acid polymer. Peterson et al. is directed to the covalent attachment of a bioactive, not the non-covalent protection/attachment of active agents. As the currently amended claims are directed to non-covalent attachment the rejection over Peterson et al. is respectfully traversed.

35 U.S.C. §103(a)

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 57-58, 61, 63-65, 67-70 and 72-75 were rejected under 35 U.S.C. 103(a) as obvious in view of Peterson et al. (as described above) in view of Latham et al. ('227) and Kramer et al. Again, Applicants have amended the claim to recite the active agent is “non-covalently protected”. Each reference cited by the Examiner is directed to covalent attachment of the active agent to an amino acid sequence. Therefore, one would not be motivated to use

alone or in combination the references to arrive at the claimed invention. Indeed, none of the references suggest an advantage may be derived from non-covalent attachment/protection.

Prior art references in combination do not make an invention obvious unless something in the prior references would suggest the advantage to be derived from combining their teachings. *In re Sernaker*, 217 U.S.P.Q. 1, 6 (Fed. Cir. 1983). There must be something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination. *Lindemann v. Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 221 U.S.P.Q. 481, 488 (Fed. Cir. 1984). *Interconnect Planning Corporation v. Feil, et al.*, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). In the present case there is no such motivation. This is particularly true given the recitation in Applicant's claims to non-covalent protection.

Each of the claims 55, 57-61, 63-94 and 96-107 are dependent claims on claims 54 and/or 95, and therefore incorporate all of the limitations of Claim 54 and 95 in addition to the further limitations set forth in the dependent claims at issue. As stated above, a proper *prima facie* obviousness rejection requires that the prior art reference(s) must teach or suggest all of the claim limitations. For the reasons set forth above, Peterson et al. in view of Latham et al. and Kramer et al. does not render obvious the claims. As stated in the M.P.E.P., "[i]f an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious." See M.P.E.P. § 2143.03 (citing *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988)).

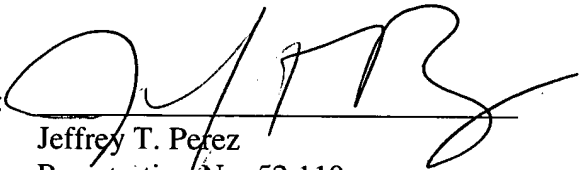
For all the reasons discussed above, Applicant's claims are patentable in view of the references of record. The rejection is respectfully traversed.

No additional fees are believed to be necessary in connection with the filing of this paper.
However, in the event any fees are necessary, the Commissioner is hereby authorized to charge
Deposit Account 50-0206 for any such fees.

Respectfully submitted,

HUNTON & WILLIAMS LLP

By:


Jeffrey T. Perez
Registration No. 52,110

Hunton & Williams LLP
Intellectual Property Department
1900 K Street, N.W. Suite 1200
Washington, DC 20006-1109
(202) 955-1500 (telephone)
(202) 778-2201 (facsimile)

Dated: July 13, 2004